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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,774	08/26/2002	Andrew W. Heath	H0664/7003	8375

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,774	HEATH, ANDREW W.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/23/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in the present application.

Applicant's election without traverse of Group I (1-15) in the amendment filed on 5/10/04 is acknowledged.

Claims 16-19 are withdrawn from further consideration because they are drawn to non-elected inventions.

Claims 1-15 are examined on the merits herein.

Drawings

The drawings are objected to because in both Figures 1 and 4, there are two separate drawing panels in each Figure, and yet they are not properly identified (e.g., Fig. 1a and Fig. 1b). Additionally, these drawing panels are not properly described in the specification on page 11, lines 12-14 and lines 23-24. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "said transfection" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. This is because there is no recitation of any transfection in claim 12 from which claim 15 is dependent. The metes and bounds of the claim are not clearly determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4, 6-9, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaussabel et al. (Infection and Immunity 67:1929-1934, 1999).

Chaussabel et al. teach a method of transfecting mouse 3T3 fibroblasts with a gene encoding CD40L (CD40L is also known in the art as CD154), wherein the complete mCD40L-cDNA was cloned into pCI-neo vector and mCD40L-expressing cells

were selected on the basis of growth in the presence of G418 sulfate and flow cytometry (see page 1930, col. 1, first full paragraph).

As the method taught by Chaussabel et al. has the same single step (transfecting a cell which does not naturally express CD154 with a nucleic acid molecule encoding CD154) as the method of claims 1, 3-4 and 6-9; and it also has the same method steps recited in claims 12 and 15 coupled with the fact that CD154 has not been shown to be expressed in somatic cells other than those which are closely associated with the immune system (e.g., T cells, mast cells, basophils, eosinophils, dendritic cells and monocytes); the method disclosed by Chaussabel et al. is indistinguishable from the methods as claimed by Applicants.

Accordingly, Chaussabel et al. anticipate the instant claims.

Claims 1-9 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kipps et al. (WO 98/26061; IDS).

Kipps et al. teach expression vectors containing accessory molecule ligand genes and methods for introducing those genes into normal and malignant antigen presenting cells (human cells included) in both *in vitro* and *in vivo* (see page 7, lines 11-30; page 9, lines 3-33). Among the accessory molecule ligand genes taught by Kipps et al. is CD40 ligand (encoded by cDNA of SEQ ID NOs:1-2 or any gene which is homologous or hybridizes with the aforementioned sequences, see pages 22-23), and among cells to be genetically modified are Langerhans cells, Kupffer cells, muscle cells, skin cells, stromal cells, connective tissue cells, fibroblasts (page 10, line 16 continues

to line 5 of page 11). Genetic vectors such as plasmids, phages, viruses are used for (page 21, lines 16-24). Kipps et al. specifically teach that cells expressing exogenous human or mouse CD40 ligand can be selected for by FACS after incubation with the appropriate components in an exemplification using CLL and HeLa cells (see page 62, lines 6-20).

The teachings of Kipps et al meet every limitation of the claims, therefore the reference anticipates the instant claims.

Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Edge (US 2002/0127205 with an effective filing date of 8/31/1998).

Edge teaches a method for preparing compositions comprising genetically modified cells which express at least one immunoregulatory molecule, wherein the immunoregulatory molecule is expressed on the surface of the cells or it is secreted, and wherein the expressed immunoregulatory molecule is capable of inhibiting T cell activation and/or natural killer mediated immune response against the genetically modified cells upon transplantation into a recipient subject (see abstract). Among the immunoregulatory molecules that Edge disclosed are soluble CD40L (CD40L is also known in the art as CD154) as well as CD40L (page 1, paragraph 0010; page 5, paragraph 0059, respectively); and cells such as pancreatic cells, kidney cells, cardiac cells, muscle cells, liver cells, lung cells, endothelial cells, eye cells, skin cells, ear cells, hair follicle cells and others from human or non-human sources are genetically modified (see page 1, paragraph 0015 and page 3, paragraph 0049). Edge further teaches that

the cell is genetically modified by introducing genetic material (e.g., RNA, DNA, cDNA, expression plasmid vector, viral vector containing partial viral genome; see page 8, paragraph 0080 and examples) and that the expression of an immunoregulatory molecule is under the control of a tissue specific promoter such as an albumin promoter for liver specific expression, insulin regulatory elements for pancreatic islet cell-specific expression and others (page 8, paragraph 0079). Edge teaches specifically that genetically modified can be selected using selectable markers which confer resistance to drugs such as neomyocin, G418, hygromycin and methotrexate (page 9, paragraph 0088).

The teachings of Edge meet every limitation of the instant claims. Therefore, Edge anticipates the instant claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Quang Nguyen, Ph.D.

DAVID GUZO
PRIMARY EXAMINER